ArthroCare CORPORATION

MAR 2 8 2002

510(k) Summary
ArthroCare Corporation
ENTec® Plasma Wands™

K014290

General Information

Manufacturer:
ArthroCare, Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person:
Bruce Prothro
Vice President, Regulatory Affairs, Quality Assurance, and Clinical Research

Date Prepared: December xx, 2001

Device Description

Trade Name: ENTec® Plasma Wands™

Generic/Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

- ENTec Coblator™ Plasma Surgery System — K973478, K000036, K000778, and K011279
- Somnus Somnoplasty System — K982717
- Ethicon PowerStar Bipolar Scissors — K981361
- Ellman Surgitron IEC II — K001253
- Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAC) Surgical Lasers — K011703
- Medtronic Xomed Monopolar Energized Blade — K002987

Intended Use

The ENTec Plasma Wands are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

Product Description

The ENTec Plasma Wands are bipolar, high frequency electrosurgical devices designed to be used in conjunction with the ENTec Coblator Plasma Surgery System.

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials incorporated, product specifications, and energy requirements of those systems. The expansion of the indications to include specific ENT procedures does not raise any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance, and Clinical Research
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Re: K014290
Trade/Device Name: ENTec® Plasma Wands™
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 27, 2001
Received: December 28, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: ENTec® Plasma Wands™
510(k) Number: K014290

Indications for Use:
The ENTec Plasma Wands are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

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- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014290